

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

In re: Oxycontin Antitrust Litigation	)	
	)	04-MDL-1603 (SHS)
	)	
COMMONWEALTH OF KENTUCKY, <i>ex rel</i>	)	This document relates to:
JACK CONWAY, ATTORNEY GENERAL, <i>et al.</i>	)	
	)	1:08-CV-3380-SHS
Plaintiffs,	)	
	)	
v.	)	
	)	
PURDUE PHARMA, L.P., <i>et al.</i> ,	)	THIS DOCUMENT WAS
	)	FILED ELECTRONICALLY
Defendants.	)	VIA CM/ECF
	)	

**MEMORANDUM IN SUPPORT OF PLAINTIFFS'**  
**RENEWED MOTION TO REMAND**

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The Plaintiffs, the Commonwealth of Kentucky ("the Attorney General"), and Pike County, Kentucky ("Pike County"), in support of their Motion to Remand, do hereby state as follows:

## **I. INTRODUCTION AND BACKGROUND**

This case was originally filed on behalf of the Commonwealth of Kentucky and Pike County, Kentucky in the Pike County Circuit Court on October 4, 2007, and the First Amended Complaint ("FAC") was subsequently filed in the Pike County Circuit Court on October 10, 2007. Thereafter, on October 29, 2007, Defendants removed the case to United States District Court for the Eastern District of Kentucky, claiming federal subject matter jurisdiction under 28 U.S.C.A. §§1331, 1441, and 1446, respectively. The case was then transferred to the Southern District of New York and consolidated with unrelated patent and antitrust actions under the title *In Re: Oxycontin Antitrust Litigation*. That litigation has been stayed since March 30, 2006 pursuant to the Court's order. As such, the Plaintiffs' complaint has sat dormant for close to eighteen months due to Defendants' removal to and consolidation with unrelated, stayed litigation in the Southern District of New York.

The gravamen of Plaintiffs' complaint is that Defendants misled medical providers and others through misrepresentations or omissions regarding the appropriate uses, risks and safety of Oxycontin<sup>1</sup> in violation of state law, including the Kentucky Medicaid Fraud statute, K.R.S. § 205.8463, the Kentucky False Advertising statute, K.R.S. § 517.030 and K.R.S. § 446.070, and common law fraud. These allegations are demonstrably unconnected to the pending patent and antitrust litigation now consolidated before this Court.

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<sup>1</sup> Oxycontin is an opioid analgesic drug sold in tablet form which is purportedly intended as a controlled-release oral form of oxycodone hydrochloride. It is approved for use in the management of moderate to severe pain. Because of its highly addictive nature which may lead to severe psychological and/or physical dependence, and its high potential for abuse, Oxycontin is a federally controlled Schedule II drug.

In their Notice of Removal (“NR”), Defendants aver that “Congress has entrusted the Department of Health and Human Services with the sole power to determine the circumstances under which a state can exclude from its Medicaid formulary a covered outpatient drug subject to a rebate agreement....” NR at 3-4. Defendants also argue that “Congress has entrusted the Food and Drug Administration (“FDA”) with sole power to determine what medicines can be marketed in the United States, the sole power to determine the content of warning labels, and the sole power to enforce the Food Drug and Cosmetic Act (“FDCA”).” NR at 4. Defendants include such verbiage to “muddy the waters” regarding the substance of this lawsuit. Defendants attempt to create federal subject matter jurisdiction simply by stating that Plaintiffs’ claims “raise substantial questions of federal law under the federal Medicaid statute because they depend upon the interpretation and application of the federal statutory provisions that govern what drugs can be included in or rejected from coverage by state Medicaid Programs, including Kentucky’s, and because federal funds constitute the majority of Kentucky’s Medicaid funds, which funds are at issue in this lawsuit.” NR at 8. But Plaintiffs’ claims do no such thing.

Let us be clear: this case is not about coverage of an outpatient drug under the Medicaid Act, and it is not it about the FDCA. This case is about whether state entities may recover under *state law* for Defendant’s failure to properly inform the public about certain risks associated with the outpatient drug Oxycontin. Plaintiffs’ well-pleaded complaint of state law claims renders the Defendants’ Notice of Removal improper under current federal removal law. Accordingly, this case should be remanded to the Pike County Circuit Court.

In further support of their Notice of Removal, Defendants extensively cite various provisions of the FDCA, as well as FDA regulations, as the bases for the affirmative defense of preemption asserted in their answers. However, the Defendants’ position—that the affirmative

defense of preemption establishes federal question jurisdiction—is without merit. In two cases raising issues nearly identical to the case at bar, the respective federal courts remanded those cases to state court due to a lack of subject matter jurisdiction. Both courts acknowledged that removal is not proper if based on a defense or an anticipated defense which is federal in nature. See *McCallister v. Purdue Pharma, LP*, 164 F.Supp.2d 783 (S.D. W.Va. 2001); *State of West Virginia ex rel Darrell V. McGraw, Jr., v. Purdue Pharma, et al*, United States District Court for the Southern District of West Virginia, Civil Action 1:01-0557.<sup>2</sup> Recent Supreme Court case law also undercuts Defendants’ preemption argument. See generally *Wyeth v. Levine*, 555 U.S. \_\_\_, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). Furthermore, it has long been held that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim arising under federal law. Defendants’ removal of the complaint to the Eastern District of Kentucky, and the subsequent transfer to and consolidation in the Southern District of New York, are without legal support.

## II. ARGUMENT

### A. The Removal Statutes and Legal Standard.

28 U.S.C. § 1331 provides, “The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws or treaties of the United States.” 28 U.S.C.A. §1441(a) through (c) likewise permits removal of a case from state court founded on a claim or right arising under the Constitution, treaties or laws of the United States, and also “[w]henever a separate and independent claim or cause of action is joined with one or more otherwise non-removable claims or causes of action, the entire case may be removed and the district court may

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<sup>2</sup> In this case Judge Farber remanded an OxyContin case filed by the Attorney General of West Virginia similar to the one before the Court. A copy of the unpublished opinion in that case is attached as Exhibit A.



determine all issues therein, or in its discretion, may remand all matters in which State law predominates.” 28 U.S.C.A. §1441(c). 28 U.S.C. § 1447(c) provides in relevant part “. . . If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case **shall** be remanded (emphasis added).”

Defendants’ burden to justify removal is a heavy one. Federal courts disfavor depriving a litigant, particularly a sovereign such as the Commonwealth of Kentucky, of its choice of forum within which to litigate purely state law claims. *Ahearn v. Charter Township of Bloomfield*, 100 F.3d 451, 454 (6th Cir. 1996). In *Ahearn*, the court stated:

Removing defendants bear the burden of establishing federal subject-matter jurisdiction. Due regard for state governments’ rightful independence requires federal courts scrupulously to confine their own jurisdiction to precise statutory limits.

*Id.* (citations omitted).

The burden of establishing jurisdiction is upon the defendant as the removing party. *Gafford v. Gen. Elec. Co.*, 997 F.2d 150, 155 (6<sup>th</sup> Cir. 1993); *Her Majesty The Queen In Right of The Province of Ontario v. City of Detroit*, 874 F.2d 332, 339 (6<sup>th</sup> Cir. 1989). It is the defendant’s burden to establish that removal is proper, and all doubts are to be resolved in favor of the state court’s jurisdiction. *Ratliff v. Merck & Co., Inc.*, 359 F.Supp. 2d 571, 574 (E.D. Ky. 2005). *See also Iulianelli v. Lionel, L.L.C.*, 183 F. Supp. 2d 962, 968 (E.D. Mich. 2002); *Hollenbeck v. Burroughs Corp.*, 664 F. Supp. 280, 281 (E.D. Mich. 1987).

In determining removal jurisdiction under §1441, federal courts apply the “well-pleaded complaint” rule which provides that federal jurisdiction exists only when a federal question is clearly presented on the face of the plaintiff’s properly pleaded complaint. *Long v. Bando Mfg. of America, Inc.*, 201 F.3d 754, 758 (6<sup>th</sup> Cir. 2000). “The [well-pleaded complaint] rule makes the plaintiff the master of the claim; he or she may avoid federal jurisdiction by exclusive

reliance on state law.” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392, 107 S.Ct. 2425, 2429, 96 L.Ed.2d 318 (1987). The fact that a wrong asserted in the complaint could be addressed under either state or federal law does not ordinarily diminish the plaintiff’s right to choose a state law cause of action. *Alexander v. Electronic Data Systems Corp.*, 13 F.3d 940, 943 (6<sup>th</sup> Cir. 1994).

Failure to rigorously apply these principles can lead to years of meaningless litigation, as the Seventh Circuit stressed in *Hart v. Terminex International*, 336 F.3d 541, 544 (7th Cir. 2003). There, the court concluded, after eight years of federal-court litigation, that the parties were not diverse and hence, all the rulings in the case were a nullity as a result of improper removal. *Id.*

Plaintiffs urge the Court to remand this case to state court in to order to avoid unnecessary litigation of state law claims in the federal courts based upon the prevailing case law.

**B. Federal Question Jurisdiction Under *Grable* Is Not Applicable Here.**

Defendants cite a number of cases in support of their notice of removal. Importantly, they give only cursory attention to the seminal case regarding federal question removal. Further, their authority on the remainder of cases cited is inapposite to remand law in the federal courts in Kentucky and the Sixth Circuit. Accordingly, these cases can be distinguished.

First, in *Grable & Sons Metals Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005), the Supreme Court found federal jurisdiction in a case involving an action to quiet title in which the meaning of a provision of the Internal Revenue Code was an “essential element of the claim.” In support of its holding the Court explained: “[F]ederal jurisdiction demands not only a contested federal issue, but a substantial

one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum.” *Id.* at 313.

The court went on to state that “even when the state action discloses a contested and substantial federal question, the exercise of federal jurisdiction is subject to a possible veto.” *Id.* The court refrained from formulating a “‘single, precise, all-embracing’ test for jurisdiction over federal issues embedded in state law claims.” *Id.* at 314 (citing *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 821, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988) (Stevens, J., concurring)). The Court similarly noted its prior holding in *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986), which disclaimed the adoption of any bright line rule. *Grable*, 545 U.S. at 317.

In *Merrell Dow*, which arose in the Sixth Circuit, plaintiffs sued a drug manufacturer, alleging presumptive negligence under state law because the drug company violated the branding provision of the federal Food Drug and Cosmetic Act. The court concluded that federal jurisdiction was lacking in the absence of a federal, private cause of action: “[T]he congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently ‘substantial’ to confer federal-question jurisdiction.” *Merrell Dow*, 478 U.S. at 814.

The *Grable* court further explained:

The absence of any federal cause of action affected *Merrell Dow*’s result two ways. The Court saw the fact as worth some consideration in the assessment of substantiality. But its primary importance emerged when the Court treated the combination of no federal cause of action and no preemption of state remedies for misbranding as an important clue to Congress’ conception of the scope of jurisdiction to be exercised under §1331. The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction

over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues.

*Grable*, 545 U.S. at 318.

When confronted by the same *Grable* arguments Defendants raise here, the court in *Thomas v. Friends Rehabilitation Program, Inc.*, 2005 WL 1625054 at \*3 (E.D. Pa) (July 11, 2005) held:

In *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, the Supreme Court held that “a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim” arising under federal law. 478 U.S. 817. That is precisely the case here. Moreover, the Supreme Court has recently referred to a state-law negligence claim that cites a federal statute to establish a defendant’s duty to the plaintiff as the classic example of what does *not* raise a federal question.

*Id.* (Citations omitted)(emphasis in original).

Moreover, state courts are generally presumed competent to interpret and apply federal law. *Mikulski v. Centerior Energy Corporation*, 501 F.3d 555, 560 (6<sup>th</sup> Cir. 2007). *See also Hays v. Cave*, 446 F. 3d 712, 714 (7<sup>th</sup> Cir. 2006) (noting “there is nothing unusual about a court having to decide issues that arise under the law of other jurisdictions; otherwise there would be no field called ‘conflict of laws’ and no rule barring removal of a case from state court to federal court on the basis of a federal defense”).

In the instant case, none of the statutes cited by the Defendants contain a private right of action, thereby yanking the “welcome mat” to federal question jurisdiction as anticipated by *Merrell Dow* and *Grable*. Further, as dictated by *Grable* as being necessary for federal jurisdiction, Plaintiffs’ state law claims as alleged in their First Amended Complaint are not sufficient to create a substantial federal question to support removal to federal court.

**C. The “Arising Under” Requirement Has Not Been Met.**

“A suit arises under the law that creates the cause of action.” *McCallister v. Purdue Pharma*, 164 F.Supp.2d at 788 (citing *Franchise Tax Bd of the State of Cal. v. Constr. Laborers Vacation Trust for S. Cal.* 463 U.S. 1, 8-9, 103 S.Ct. 2841, 77 L.Ed.2d 420 (1983)). “[B]ecause the ‘arising under’ language of §1441(b) is almost identical to the language of 28 USC §1331, the scope of removal jurisdiction based on the existence of federal question under §1441(b) is considered to be identical to the scope of federal question jurisdiction under §1331.” *Eastman v. Marine Mechanical Corp.*, 438 F. 3d 544, 549 (6th Cir. 2006) (citing *Long v. Bondo Mfg. of Am., Inc.*, 201 F3d 745, 757-58 (6<sup>th</sup> Cir. 2000)). Whether a given civil action arises under the law of the United States thereby invoking federal jurisdiction necessarily depends on the application of the well-pleaded complaint rule. Under that test, a cause of action arises under federal law when the plaintiff’s well-pleaded complaint raises the issue of federal law. *McCallister*, 164 F.Supp.2d at 788. “[T]he party who brings a suit is master to decide what law he will rely upon.” *Eastman*, 430 F.3d at 550 (citing *The Fair v. Kohler Die and Specialty Co.*, 228 U.S. 22, 25, 33 S.Ct. 410, 57 L.Ed. 716 (1913)).

The “arising under” gateway into federal court has two distinct portals. The well-worn thoroughfare admits litigants whose causes of action are created by federal law, that is, where federal law provides a right of relief. *Id.* That is not the case here. Neither the FDCA nor the Medicaid Act provides such passage. The Court in *Grable* analyzed the second portal—the “path less traveled”—and recognized that in certain cases federal question jurisdiction will lie over state law claims that implicate significant federal issues or turn on substantial issues of federal law. *Grable*, 545 U.S. at 312. However, “the mere presence of a federal issue in a state

law case does not automatically confer federal-question jurisdiction.” *Merrell Dow*, 478 U.S. at 813.

In this instance, Defendants were sued in Pike County Circuit Court, under applicable state law (*See* FAC, Counts 1-13, at 30-53). Plaintiffs claims are brought under applicable Kentucky statutory law found under K.R.S. § 205.8463 (the Kentucky Medicaid Fraud Statute); K.R.S. § 517.030 (the Kentucky False Advertising Statute); and Kentucky common law. Nowhere in the First Amended Complaint is a federal cause of action asserted, because none exists, and thus, removal to federal court is improvident.

In a subsequent case which refined its holding in *Grable*, the Supreme Court in *Empire Healthcare Choice Assurance, Inc. v. McVeigh*, 126 S.Ct. 2121, 2137, 165 L.Ed.2d 313 (2006) (citation omitted), summarily stated that “*Grable* emphasized that it takes more than a federal element to open the ‘arising under’ door. This case cannot be squeezed into the slim category *Grable* exemplifies.” Nor, does it seem, can the instant case. As Judge Forrester in *In Re Air Crash at Lexington, Kentucky, August 27, 2006*, 486 F.Supp.2d 640, 656 (E.D. Ky. 2007), succinctly stated: “[A] defendant cannot, merely by injecting a federal question into an action that asserts what is plainly a state law claim, transform that action into one arising under federal law, thereby selecting the forum in which the claim shall be litigated. If a defendant could do so, the plaintiff would be master of nothing.”

Plaintiffs, as masters of their claims, alleged only state statutory and common law claims. This is clear and unequivocal in their First Amended Complaint. Defendants’ Notice of Removal is nothing more than an improper attempt to select a forum for which no subject matter jurisdiction exists. Defendants’ Notice of Removal should be rejected in favor of remand to Pike County.

#### **D. Preemption Does Not Apply in This Case**

Defendants argue that the Plaintiffs' claims are preempted by federal law. However, both a recent Supreme Court decision and a review of the applicable federal statutory law show that it was never the intention of Congress to preempt state court actions such as the instant case. Further, no federal court has extended federal jurisdiction to encompass state tort actions dealing with health and safety issues such as those alleged by the Plaintiffs.

##### **1. *Wyeth v. Levine***

During the pendency of this action, the United States Supreme Court announced their decision in *Wyeth v. Levine*, 555 U.S. \_\_\_, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). *Wyeth* involved state law claims revolving around Phenergan, an anti-nausea drug, and alleged defects in the warning label that accompanied the drug. *Wyeth*, the pharmaceutical company that had both created and marketed Phenergan, argued that plaintiff Levine's state law claims, specifically those revolving around Phenergan's labeling, had been preempted by federal law. In finding that the FDCA did not preempt Levine's state law claim and that it was not impossible to comply with state law duties and federal rules regarding drug labels, the Court noted that Congress had not expressly or impliedly preempted state law causes of action, stating:

“If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70 year history. But despite its 1976 enactment of an express preemption provision for medical devices, see §521, 90 Stat. 574 (codified at 21 U. S. C. §360k(a)), Congress has not enacted such a provision for prescription drugs.”

*Wyeth*, 129 S.Ct. at 1200. The Court ultimately concluded:

“We conclude that it is not impossible for *Wyeth* to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.”

*Id.* at 1204.

The lack of an express preemption provision in the FDCA is supremely important in this case, because the causes of action are nearly identical. The Defendants have argued that federal law would preempt Plaintiffs' claims; however, the Supreme Court disagrees in *Wyeth*. Clearly this cause of action can and should be maintained in the state courts, and accordingly should be remanded on this basis.

## 2. Preemption Generally

It is well-settled case law that “a case may *not* be removed to federal court on the basis of a federal defense, including the **affirmative defense of preemption**, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue.” *In Re Air Crash*, 486 F.Supp.2d at 644 (quoting *Roddy v. Grand Trunk Western Railroad, Inc.*, 395 F.3d 318, 322 (6<sup>th</sup> Cir. 2005) (emphasis added). A federal court in Kentucky recently opined that “a defendant may not rely on a **defense** arising under federal law as grounds for removal.” *Kentucky v. China Tobacco Anyang Cigarette Factory*, 383 F.Supp.2d 917, 918 (E.D. Ky. 2005) (emphasis added) (citation omitted). There are several types of preemption of state law under the Supremacy Clause, and for the sake of brevity, only two—express and implied—appear to be alleged in the instant case and are described below.

## 3. Express Preemption

“Congress may expressly state its intention that a federal statute will supplant substantive state law and/or state law remedies.” *In Re Air Crash*, 486 F.Supp. 2d at 645. In the instant case, there is no such intention expressed by Congress, nor does any case law exist to support such a finding regarding the federal statutes cited by the Defendants in their Notice of Removal.



As there is no express preemption found within the Medicaid statutes, the FDCA, or the FDA statutes, then there is no basis for removal.

#### 4. Implied “Ordinary” Preemption

Implied preemption is referred to by other courts variously as “ordinary preemption” or “field preemption.” Implied preemption may take one of two forms, either “ordinary” or “complete.” From the Defendants’ Notice of Removal, it appears that complete preemption forms the basis for their removal of this matter to federal court. That basis is flawed as there is no support for Defendants’ allegations of complete preemption under federal case law.

First, ordinary preemption requires the application of substantive federal law. “If the federal law that purportedly preempts state law is alleged in a well-pleaded complaint, that will provide the basis for federal jurisdiction. Ordinary preemption will not, however, permit removal jurisdiction if the plaintiff chose to frame his claim solely on state law, and preemption is raised only as a defense by the defendant.” *In Re Air Crash*, 486 F.Supp. 2d at 647. Since Plaintiffs have alleged state law causes of action in their complaint, and since Defendants have **only** raised preemption as a defense, ordinary preemption does not apply here.

Complete preemption, which Defendants seek herein, involves preemption of state substantive law as well as state causes of action. *Id.* Complete preemption applies where “the preemptive force of a statute is so ‘extraordinary’ that it converts an ordinary state common law complaint into one stating a federal claim for purposes of the well-pleaded complaint rule.” *Caterpillar*, 482 U.S. at 393 (quotations and citations omitted). Once an area of state law is preempted, any claim purportedly based on the preempted state law is considered, from its inception, a federal claim, and therefore arises under federal law. *Id.* A review of the case law indicates that complete preemption jurisdiction has been exercised sparingly by the federal

courts. In *Roddy*, the Court noted only three instances in which the Supreme Court has recognized complete preemption: § 301 of the Labor Relations Management Act, 1947 (“LRMA”), 29 U.S.C. § 185; § 502 (A) of the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. § 1001, et seq.; and § 30 of the National Bank Act, 12 U.S.C. §§ 85 and 86. *In Re Air Crash*, 486 F.Supp.2d at 648 (citing *Roddy*, 395 F.3d at 323). *See also McCallister*, 164 F.Supp.2d at 790; *Mikulski*, 501 F.3d at 563.

The Sixth Circuit, however, has extended the limited rule of preemption to the National Flood Insurance Act in *Gibson v. Am. Bankers Ins. Co.*, 289 F.3d 943, 947 (6<sup>th</sup> Cir. 2002), but specifically declined to apply the doctrine to Medical Device Amendments to the Food Drug and Cosmetic Act in *Strong v. Telectronics Pacing Sys., Inc.*, 78 F.3d 256, 259 (6<sup>th</sup> Cir. 1996). One federal court ruled recently that the FDCA does not preempt state law. In *Pennsylvania v. Eli Lilly & Company, Inc.*, 511 F.Supp.2d 576, 583 (E.D. Pa. 2007), a case analogous to this one, the court stated:

No court has held that the federal Medicaid Act or the FDCA completely preempts a state’s Medicaid recovery action for purposes of removal jurisdiction. Indeed, courts in this district have found that removal based on complete preemption by the FDCA is improper because the FDCA does not provide for civil enforcement remedies. *Id.*

Similarly, in another federal case in which the FDCA was implicated in a state law tort case, the court rejected preemption by the FDCA finding that “Congress has never spoken on preemption with respect to prescription drugs,” and ultimately holding that preemption was inappropriate. *In Re Vioxx Products Liability Litigation*, 501 F.Supp.2d 776, 785 (E.D. La. 2007). As Defendants have alleged that Plaintiffs’ state law claims arise under the FDCA and the federal Medicaid Act as the basis for their Notice of Removal, the law is clear that these claims are not preempted by federal law and should be dealt with in state court.

Defendants argue that “the federal government has a strong interest” in multiple facets of this case, all of which “have far-reaching implications for federal regulation of Medicaid reimbursement.” NR at 13-14. However, Judge Weinstein explicitly stated in a recent opinion: “In fields traditionally occupied by the states, such as health and safety regulation, there is strong presumption against federal preemption.” *In Re Zyprexa Prods. Liab. Litig.*, 489 F.Supp.2d 230, 272 (E.D. N.Y. 2007). Moreover, the *McCallister* court said:

The Court is sympathetic to Defendants’ desire for uniform and consistent interpretations of the federal statutes and extensive federal regulatory scheme under which they operate and by which they are guided. Nevertheless, the Supreme Court has rejected defensive preemption as a basis for federal removal jurisdiction, and this Court must observe the jurisdictional boundaries as they, currently, are clearly drawn.

*McCallister*, 164 F.Supp.2d at 794.

The Court in *Palkow v. CSX Transportation, Inc.*, 431 F.3d 543, 552-53 (6<sup>th</sup> Cir. 2006) stated:

[I]t is only when the federal statutory language demonstrates that Congress has manifested a clear intent that claims not only be preempted under the federal law, but also that they be removable, that they are deemed to be “completely preempted.”

*Id.*

As that Court further opined: “In other words, the complete preemption doctrine is not simply one of preemption of the law, it is a sort of ‘super’ preemption which preempts not only state law, but also creates federal removal jurisdiction—to use the jargon of the day, it is ‘preemption on steroids’.” *Id.* at 553. “The plaintiff must remain ‘master of the claim’ and the plaintiff’s choice of forum should prevail unless there is preemption on steroids.” *In Re Air Crash*, 486 F.Supp. 2d at 650 (quotations omitted). Plaintiffs’ complaint should be remanded to state court as the doctrine of complete preemption is not applicable.

**E. Permitting Removal In This Case Would Disturb the Established Work Load Between State and Federal Courts.**

Both *Merrell Dow* and *Grable* agree that in the absence of a federal private right of action it could be assumed that Congress did not intend to confer federal jurisdiction on a class of cases, which would result in a reapportionment of the traditional responsibilities between state and federal courts. Both cases referred to the disruption in the state and federal courts that would occur if state tort or statutory claims were removable simply because they relied on an interpretation of a federal statute. *See Merrell Dow*, 478 U.S. at 810; *Grable*, 545 U.S. at 313-14.

Yet this alleged need for a federal forum is the basis upon which Defendants urge the Court to permit removal. The case brought by the Plaintiffs is nothing more than a series of state tort and state statutory claims. These are the very kinds of claims that both *Merrell Dow* and *Grable* held were not removable even assuming that these claims are dependent on the interpretation of a federal statute. These types of claims relating to health and safety have been soundly rejected by the federal courts. As the Court stated in *Merrell Dow*, “[g]iven the significance of the assumed congressional determination to preclude federal private remedies, the presence of the federal issue as an element of the state tort is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system.” *Merrell Dow*, 478 U.S. at 814. Or, as the Court reiterated in *Grable*: “One only needed to consider the treatment of federal violations generally in garden variety state tort law . . . A general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal courts.” *Grable*, 545 U.S. at 318-19. *See also Utah v. Eli Lilly*, 509 F.Supp. 2d 1016, 1024 (D. Utah 2007) (finding that “an exercise of federal jurisdiction would disturb the

congressionally approved balance of federal and state judicial responsibilities”); *Mikulski*, 501 F.3d at 573 (finding “the exercise of [federal] jurisdiction over this type of lawsuit would impermissibly disrupt the congressionally approved balance of federal and state judicial responsibilities”).

**F. Cases Cited by Defendants are Inapposite.**

First, Defendants rely on *State of West Virginia ex rel. Darrell V. McGraw, Jr. v. Eli Lilly & Co., Inc.*, 476 F.Supp.2d 23 (E.D.N.Y. 2007), in support of their contention that payments for drugs as part of its participation in the federal Medicaid Program presented substantial and disputed federal question, and thus is a basis for removal. Two federal courts since then have rejected identical arguments. *See, e.g., Pennsylvania v. Eli Lilly & Company, Inc.*, 511 F.Supp.2d 576 (E.D. Pa. 2007)(“[T]he fact that a federally created program, Medicaid, serves as the initial source of the funds which the Commonwealth seeks to recover does not without more, confer federal jurisdiction.”); *Utah v. Eli Lilly and Company*, 509 F.Supp.2d 1016 (D. Utah 2007). *See also Commonwealth of Massachusetts v. Phillip Morris, Inc.*, 942 F. Supp. 690, 695 (D. Mass. 1996) (“[T]he presence of an overarching federal influence on a program does not make into a federal question a suit brought under state law....”).

Moreover, the Defendants selectively cite *County of Santa Clara v. Astra USA, Inc.*, 410 F.Supp.2d 1022 (N.D. Cal. 2005), as an example of a drug pricing case in which federal question jurisdiction was invoked. That case is distinguishable because the complaint also contained “Best Price” claims in the context of a federal contract, thereby heightening the federal interest in the matter. Defendants fail to mention other drug pricing cases in which the court found federal jurisdiction lacking in state law claims. Two subsequent drug pricing cases involving the average wholesale prices of drugs reimbursed under Medicaid reached different results in the

face of arguments similar to those presented by Defendants here. In *Pennsylvania v. TAP Pharmaceutical Products*, 415 F.Supp.2d 516, 524-26 (E.D. Pa. 2005), the court noted that a facial assessment of the Commonwealth's exclusively state-law causes of action precluded removal on federal-question jurisdiction and held that the term "average wholesale price" (AWP) was not actually disputed because the Commonwealth did not premise its claim on the construction of these words as they appear in the applicable Medicare statute and regulations. Similarly, the court in *Hawaii v. Abbott Laboratories, Inc., et al.*, 469 F.Supp.2d 842, 855 (D. Hawaii 2006) found federal jurisdiction lacking when it held:

The resolution of the meaning of AWP will have little effect on the future viability of the Medicare program since the AWP standard has been abandoned. While it may well be the case that the meaning of AWP is a substantial issue for the parties, it is no longer a substantial issue for the federal government.

*Id.* See also *McCallister*, 164 F. Supp. 2d 783 (S.D. W.Va. 2001) (holding that interpretive issues under the Controlled Substances Act and the FDCA are insufficient to provide removal jurisdiction in the absence of a federally mandated cause of action); *Greene v. Novartis Pharmaceuticals Corporation*, 2007 WL 3407429 (MD. Ga. Nov. 14, 2007).

Despite the selective minority opinion cases cited by the Defendants, the overwhelming consensus of the majority of federal courts is that the claims of the Plaintiffs should be left for state court adjudication despite the fact that some federal statutes may be implicated as part of the defense or otherwise.

**G. The Class Action Fairness Act is Inapplicable as No Class Allegations are Made in the Plaintiffs' First Amended Complaint**

Plaintiffs filed their Complaint on October 4, 2007, in the Pike Circuit Court. However, on October 10, 2007, prior to the filing of any responsive pleading by the Defendants, Plaintiffs filed their First Amended Complaint pursuant to Kentucky Civil Rule ("CR") 15.01. CR 15.01

mandates that “[a] party may amend his pleading once as a matter of course at any time before a responsive pleading is served.” For those reasons, the terms and language found in the First Amended Complaint control the Plaintiffs’ claims and causes of action asserted herein.

A complete and comprehensive reading of the First Amended Complaint makes it clear that the Commonwealth of Kentucky has not inferred and did not intend to infer that a class action was being filed or anticipated. Plaintiffs further affirmatively state that the Commonwealth of Kentucky has no intention of pursuing a class action in this civil action for the private claims of Kentucky citizens who have been harmed by the actions of the Defendants.

Because the First Amended Complaint is clear that no class action is alleged, combined with the affirmative statements of the Plaintiffs that no class action is alleged or anticipated, the Defendants have failed to meet their burden of proof to overcome the well-settled presumption against removal jurisdiction. Defendants have attempted to insinuate that the new provisions of 28 U.S.C. § 1332(d) have expanded federal court jurisdiction and that it should be interpreted broadly.

However, this expansion set forth in the Class Action Fairness Act has neither alleviated the Defendants’ substantial burden of persuasion nor lessened the presumption against removal jurisdiction. *Rodgers v. Central Locating Service, LTD.*, 412 F.Supp.2d 1171, 1176 (W.D. Wash. 2006). Plaintiffs contend that no matter how “broadly” the Act should be interpreted, there is nothing in the provisions or comments from Congress which make it acceptable to infer a class action where none clearly exists for the purpose of removing this action to Federal Court.

**1. The True Nature of the Allegations Found within the First Amended Complaint are Misrepresented by the Defendants**

The Defendants have taken great pains to excise certain phrases and portions of the complaint out of its context to insinuate that the Attorney General’s office is attempting to bring

a class action on behalf of all Kentucky citizens who have a private claim of action against the Defendants.<sup>3</sup> However, the only way that Defendants can support this allegation is to cite these phrases out of context from the complaint as a whole. When read in context with the language surrounding these excerpts, it is clear that the Attorney General's office is only seeking recovery for reimbursement of **state governmental** monies which have been unnecessarily expended due to the actions of the Defendants.

Under Kentucky law, the Attorney General is the "chief law officer" of the Commonwealth of Kentucky and the "protector" of the State Treasury. Whenever the Attorney General believes there has been an improper payment from the State Treasury he has a mandatory duty to institute an action to recover the monies. *Strong v. Chandler*, 70 S.W.3d 405, 410 (2002); K.R.S. § 15.020. When the language of the complaint indicates that the Attorney General's office is representing Kentucky's citizens, it refers to the monies paid by Kentucky citizens in the form of taxes which are then disbursed from the State Treasury through many avenues, including the Kentucky Medicaid program. As each Kentucky citizen is entitled to a government which spends its money responsibly and takes necessary legal action when State Treasury funds are improperly diverted from State goals, the Commonwealth of Kentucky is charged with taking legal action to recover those monies paid by citizens for the benefit of Kentucky. Paragraph 6 of the Plaintiffs' First Amended Complaint states:

Whenever the Attorney General believes there has been an improper payment from or credit against the State Treasury he is authorized by Section 91 of the Kentucky Constitution, KRS §15.020, KRS § 15.060, KRS § 446.070, and Kentucky common law, including the Attorney General's *parens patriae* authority, to bring this action on behalf of the Commonwealth of Kentucky and its citizens and to institute an action to recover the monies.

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<sup>3</sup> It is ironic that the Defendants are attempting to infer a class action allegation in this civil action as they have vigorously and successfully fought previous attempts to certify a class action in this jurisdiction. *See, e.g., Gevedon v. Purdue Pharma*, 212 F.R.D. 333 (E.D. Ky. 2007).



First Amended Complaint, paragraph 6.

In fact, even the language cited by the Defendants in their motion is unequivocal that the relief sought by the Plaintiffs is for governmental payments, not private claims. Had the Defendants bothered to review the statutory law quoted in their Notice of Removal, it would be clear that these statutes refer to the authority of the Attorney General's office as chief legal officer (K.R.S. § 15.020) to pursue actions to collect and recover money due to the Commonwealth. (K.R.S. § 15.060). Similarly, K.R.S. § 446.070 is merely reflecting the statutory authority of the Commonwealth to seek civil recovery for the violation of any statute.<sup>4</sup> Nothing in any of these statutes either implies or authorizes the Attorney General's office to pursue a class action for a citizen's private claims, nor did the Attorney General's office ever intend to do so.

Likewise, when the language of the First Amended Complaint cited by the Defendants requests the reimbursement for unnecessary prescription costs incurred by consumers, the context of the complaint clearly shows that the reference is for costs incurred by consumers and paid for by the Commonwealth. The only way to interpret these sections as organizing a class action is to remove it from the language surrounding it. Plaintiffs state that it is improper and irresponsible to manipulate the plain language of the Plaintiffs' complaint to misrepresent its meaning to this Court.

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<sup>4</sup> KRS 446.070 provides: "A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

**2. Plaintiffs Do Not Intend to File a Class Action as Evidenced by the Removal of all Class Action Language in Plaintiffs' First Amended Complaint**

Plaintiffs further state that their action in filing the First Amended Complaint is also clear proof that the Plaintiffs do not intend to pursue class action relief on behalf of a large group of people or entities. When the Original Complaint was filed on October 4, 2007, language was included which would purport to present a class action on behalf of Pike County for itself and *for all other Kentucky Counties similarly situated*. Several paragraphs setting forth the parameters of the class action and the necessary pleading requirements for the pursuit of a class action were also found within the Original Complaint.

However, as a matter of right pursuant to Kentucky C.R. 15.01, before any responsive pleading was filed, the Plaintiffs amended their complaint to redact all language supporting the pursuit of a class action in this litigation. The decision to remove the class action language was made after serious discussion between Plaintiffs, and it was determined that a class action was not an appropriate avenue of recovery in this civil action.

The language of the Original Complaint clearly evidences that Plaintiffs are aware of the pleading requirements necessary to pursue a class action. These pleading requirements were purposely deleted from the First Amended Complaint, evidencing a clear intention to *not* pursue a class action. It is also clear from an examination of the Original Complaint and the First Amended Complaint that it was *never* the intention of the Commonwealth to file a class action on behalf of private citizens. Defendants' attempt herein to fabricate a class action goes against the clear intent of the Plaintiffs' complaint and should be disregarded in the Court's analysis regarding the propriety of Defendants' removal of this action to Federal Court.

**3. Plaintiffs' Claims are Not Typical and Plaintiffs are not a Representative Party for the Alleged Class Action Defendants Are Attempting to Create**

Lastly, the Plaintiffs did not intend to file a class action to represent the private claims of Kentucky citizens due to the fact that the Attorney General's claims are not typical of a private citizen's claims. This Court has extensively reviewed prior attempts at class certification for private claims relating to Oxycontin use and abuse. *See, e.g., Gevedon v. Purdue Pharma*, 212 F.R.D. 333 (E.D. Ky.). In that case, as well as in other unpublished cases cited within *Gevedon*, the Court has determined that a class action for private claims is not appropriate in the context of the litigation relating to Oxycontin. *Id.*

In view of this well-settled precedent in the Eastern District of Kentucky, it seems evident that any complaint which alleged a class action would likely fail and is discouraging to anyone who might attempt to revisit this concept with the District Court. In the instant case, not only did the Attorney General not even attempt to allege a class action for private claims, it is evident on the face of the complaint that it would be absurd to suggest such an action in view of the clear mandates of the Federal Rule of Civil Procedure 23 dealing with the prerequisites to a class action.

Federal Rule of Civil Procedure 23(a) lists four prerequisites to a Class Action, which are:

One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed.R.Civ.Pro. 23(a).

On the face of the complaint, it is clear that the Attorney General's claims and/or defenses are not typical of any claims or defenses of any class composed of private citizens as required by Rule 23(a)(3). For an alleged representative party's claim to be typical to the alleged class, it must arise "from the same event or practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." *In re American Medical Systems, Inc.*, 75 F.3d 1069, 1082 (6<sup>th</sup> Cir. 1996). "A necessary consequence of the typicality requirement is that the representative's interests will be aligned with those of the represented group, and in pursuing his own claims, the named plaintiff will also advance the interest of the class members." *Id.*

As is evident from the complaint, the Attorney General is seeking reimbursement *only* for state governmental monies paid out the State treasury erroneously for prescription expenses for Oxycontin and treatment related to Oxycontin addiction. No allegations were made in the complaint seeking reimbursement for any monies paid by private citizens, whether private payments in addition to the State Medicaid Program or otherwise. There is nothing typical in these claims to that of a private citizen. Additionally, the defenses applicable to Purdue from the Attorney General's claims are vastly different from those they might have against a private citizen's claims. The Defendants' Notice of Removal clearly lists the various defenses they would have under the Federal Medicaid, FDCA, and FDA statutes, none of which are applicable in private claims. Because the claims of the Attorney General are vastly different from the claims of private citizens, it fails the typicality requirement under Rule 23(a)(3) and is further proof that a class action was neither alleged nor intended by the Plaintiffs' First Amended Complaint. Therefore, the Defendants' arguments in favor of removal based upon the Class Action Fairness Act should be disregarded.

## **H. Resolution of the Issues in Multidistrict Litigation is Not Appropriate**

On November 1, 2007, pursuant to 28 U.S.C. § 1404(a), Defendants filed a Motion to Transfer the instant case to multidistrict litigation (“MDL”) currently pending in the Southern District of New York where a number of *unrelated* class actions filed by private third-party payors and consumers are pending (Docket No. 14). For the reasons cited above requiring remand and those articulated in the Plaintiffs’ Response to Motion for Transfer (Docket No. 16), the fact that a concurrent MDL case exists is not enough to confer federal-question jurisdiction. Several courts in similar cases have also rejected this notion. *See, e.g., Pennsylvania v. Eli Lilly and Company*, 511 F.Supp.2d at 584, n.3 (“[T]he existence of current MDL proceedings does not automatically confer subject matter jurisdiction.”); *Pennsylvania v. Tap Pharmaceutical Products, Inc.*, 415 F.Supp.2d 516, 521 (E.D. Pa. 2005) (“[T]he existence of subject matter jurisdiction cannot be resolved more efficiently or uniformly in MDL 1456 because it is undisputed that one federal court must make an individualized assessment of the jurisdictional issues in this case.”). *See also Ahearn*, 100 F.3d at 456; *In re Estate of Tabas*, 879 F.Supp. 464, 467 (E.D.Pa. 1995) (“An already-existing federal action cannot provide a mechanism for removal of a non-removable state-court action.”); *Sebring Homes Corp v. T.R. Arnold & Assocs.*, 927 F.Supp. 1098, 1101 (N.D. Ind. 1995) (existence of a separate, but related, suit in federal court is not a basis for removal); *N. Am. Van Lines, Inc. v. Coleman*, 633 F.Supp. 632, 634 (N.D. Ill. 1986) (rejecting as “wholly fanciful” the use of an already-existing federal action as a basis of removal under §1441(c)).

## **III. CONCLUSION**

Defendants have sidestepped the rule of law in Kentucky by failing to cite a single case that supports removal under any theory. Removal is improper as no substantial federal question

exists and the state causes of action are not preempted. Defendants have failed to meet their burden of establishing a plausible basis for removal. Accordingly, Plaintiffs respectfully request that the instant case be remanded to Pike Circuit Court.

Respectfully submitted,

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